UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

DONNA CHRASTECKY AND	§	
MICHAEL CHRASTECKY,	§	
Plaintiffs	§	
	§	Case No. A-19-CV-1240-LY-SH
v.	§	
	§	
C. R. BARD, INC.,	§	
Defendant	Ü	

REPORT AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

TO: THE HONORABLE LEE YEAKEL UNITED STATES DISTRICT JUDGE

Before this Court are Defendant's Motion for Complete Summary Judgment and Memorandum of Law in Support of its Motion for Complete Summary Judgment, filed August 14, 2019 (Dkt. Nos. 69 and 70); Plaintiffs' Memorandum of Law in Opposition to Defendant's Motion for Summary Judgment, filed August 28, 2019 (Dkt. No. 86); and Defendant's Amended Reply, filed September 16, 2019 (Dkt. No. 95).

I. BACKGROUND

A. The Underlying MDL

This product liability lawsuit resides in one of seven multidistrict litigations ("MDLs") involving the use of transvaginal surgical mesh to treat pelvic organ prolapse and stress urinary incontinence. The Judicial Panel on Multidistrict Litigation assigned 100,000 of these MDL cases to the Honorable Joseph R. Goodwin, United States District Judge for the U.S. District Court for the Southern District of West Virginia, Charleston Division. Dkt. No. 102. Approximately 14,000 of these cases were filed against C. R. Bard, Inc., one of the manufacturers of transvaginal surgical

mesh. See In Re: C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation, No. 2:10-CV-2187, MDL 2187 (S.D. W. Va.) (the "Bard MDL").

To manage the Bard MDL efficiently and effectively, Judge Goodwin conducted pretrial discovery and motions practice on an individualized basis. He selected approximately 300 of the Bard cases to become part of a "wave" of cases to be prepared for trial and applied to them the same scheduling deadlines, limitations on discovery, and rules regarding motion practice. *See* Pretrial Order No. 244 in the Bard MDL. Judge Goodwin has ruled on a plethora of *Daubert* motions filed by the parties, some of which are at issue in the instant case.

B. This Lawsuit

The Plaintiff in this case, Donna Chrastecky ("Plaintiff"), alleges that she suffered serious injuries after she was implanted with the Bard Align TO Urethral Support System device ("Align Device") on October 22, 2010, by Dr. Ash Dabbous and Dr. Troy Haliparn at the Louis Pasteur Surgery Center in San Antonio, Texas. Plaintiff alleges that after the implantation, she began to suffer complications, including pain, rashes, irritation, infections, numbness, tingling, and the inability to void. Although Plaintiff has had to undergo multiple surgeries to remove the Align Device, she alleges that she continues to experience constant pain, infections, the inability to maintain physical activity, depression, anxiety, and an inability to engage in intimate relations with her husband.

On October 19, 2012, Plaintiff and her husband, Michael Chrastecky (together, "Plaintiffs"), filed this lawsuit directly into the Bard MDL, alleging negligence; strict liability design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; and loss of consortium. *See* Dkt. Nos. 1 & 86-1. Plaintiffs seek compensatory and punitive damages, attorneys' fees, costs, interest, "or any other relief, monetary or equitable, to which they are entitled." Dkt. No. 86-1 at p. 34.

More than five years after Plaintiffs filed this case, the parties notified Judge Goodwin that they had reached a settlement. Dkt. No. 38. Accordingly, on October 27, 2017, Judge Goodwin ordered the case to be docketed as "inactive" and ordered the parties to file a joint motion to dismiss. *Id.* Ultimately, however, the parties were unable to reach a settlement. On February 4, 2019, Judge Goodwin returned the case to the active docket. Dkt. No. 42.

On August 14, 2019, Bard filed the instant Motion for Summary Judgment, arguing that all of Plaintiffs' claims should be dismissed because Plaintiffs have failed to establish a genuine issue of material fact regarding causation as to each of their claims. Alternatively, Bard argues that Plaintiffs' claims should be dismissed for lack of sufficient evidence to support those claims, or for failure to state a claim as a matter of law.

Before ruling on the Motion for Summary Judgment, on December 3, 2019, Judge Goodwin transferred this case to the Western District of Texas "[f]or the convenience of the parties and in order to promote the final resolution of [this case]," reasoning that the case would be concluded more expeditiously in the venue "from which [it] arise[s]." Dkt. No. 102 at p. 1. The parties had notified Judge Goodwin that the proper venue for the case would be in this District. *Id*.

On January 22, 2020, the District Court referred all pending and future motions in this case to the undersigned pursuant to 28 U.S.C. § 636(b), FED. R. CIV. P. 72, and Rule 1 of Appendix C to the Local Rules of the United States District Court for the Western District of Texas. On January 31, 2020, the Court held a status conference during which the parties informed the Court that all pending motions are ripe for disposition. Accordingly, the Court makes the following recommendations on the Motion for Complete Summary Judgment.

II. Legal Standards

Summary judgment shall be rendered when the pleadings, the discovery and disclosure materials, and any affidavits on file show that there is no genuine dispute as to any material fact

and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Washburn v. Harvey*, 504 F.3d 505, 508 (5th Cir. 2007). A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986); *Washburn*, 504 F.3d at 508. A court "may not make credibility determinations or weigh the evidence" in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *see also Anderson*, 477 U.S. at 254-55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita*, 475 U.S. at 586. Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007). Unsubstantiated assertions, improbable inferences, and unsupported speculation also are not competent summary judgment evidence. *Id.* The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports its claim. *See Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006). If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

III. ANALYSIS

Plaintiffs' lawsuit alleges negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, breach of express warranty, breach of implied warranty, loss of consortium, and a claim for punitive damages. Bard argues that it is entitled to summary judgment because Plaintiffs have failed to establish a genuine issue of material fact regarding causation in this case. Alternatively, Bard argues that Plaintiffs' claims should be dismissed for lack of sufficient evidence to support those claims, or for failure to state a claim as a matter of law. The parties agree that Texas law applies to this case.

A. Causation

As Bard correctly notes in its motion, causation is an element of all Plaintiffs' claims. *See Horak v. Pullman, Inc.*, 764 F.2d 1092, 1095 (5th Cir. 1985) (concluding that Texas law requires proof of causation for product liability claims based on negligence and strict liability theories); *Hyundai Motor Co. v. Rodriguez ex rel. Rodriguez*, 995 S.W.2d 661, 667 (Tex. 1999) ("Liability for breach of warranty requires a showing of proximate cause."). "Ordinarily, expert testimony is needed to satisfy the reasonable medical probability standard for establishing a causal link." *Anderson v. Siemens Corp.*, 335 F.3d 466, 474 (5th Cir. 2003).

Bard argues that Plaintiffs have failed to establish a genuine issue of material fact regarding causation because they have failed to offer sufficient expert testimony that the Align Device was a substantial factor in Plaintiff's alleged injuries. Specifically, Bard argues that (1) Plaintiff's only evidence of causation is the testimony of Dr. Bruce Rosenzweig, M.D., Plaintiff's medical causation expert, whose testimony should be excluded under *Daubert v. Merrell Dow Pharms.*, *Inc.*, 509 U.S. 579 (1993); and (2) even if Dr. Rosenzweig's opinions satisfied *Daubert*, his opinions are insufficient to show causation because he did not consider all of Plaintiff's preexisting medical conditions.

This Court rejected these arguments in denying Bard's Motion to Exclude Dr. Rosenzweig's testimony. *See* Dkt. No. 123. Thus, Plaintiffs may rely on Dr. Rosenzweig's testimony to show causation in this case.

In addition, Plaintiffs have offered the testimony of Dr. Ahmed El-Ghannam to show causation. As with Dr. Rosenzweig, the Court has ruled that Dr. El-Ghannam can testify as to causation in this case. *See id*.

Based on the foregoing, Bard has failed to sustain its initial burden to show that there is no evidence to support the element of causation in this case. Accordingly, Bard's Motion for Summary Judgment on this basis should be denied.

B. Design Defect

To recover for a products liability claim alleging a design defect under Texas law, a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery. *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1, 6 (Tex. 2015). "A safer alternative design is one that would have prevented or significantly reduced the risk of the injury, would not substantially impair the product's utility, and was economically and technologically feasible at the time." *Id.* at 7.

Bard argues that Plaintiffs' design defect claim fails because Plaintiffs have not presented sufficient evidence of a safer alternative design. Bard contends that Dr. Rosenzweig's opinions and testimony do not show that any of the proposed alternatives would be safer than the Align Device. The Court disagrees.

In his Expert Report, Dr. Rosenzweig testified that four specific alternative designs existed that were safer and feasible for Plaintiff. Dkt. No. 86-3 at p. 70. Dr. Rosenzweig opined that: "These safer alternative designs were capable of preventing Mrs. Chrastecky['s] injuries and

damages, as I have described in my report, that were a result of the specific design flaws of the Align Marlex polypropylene" *Id.* He further opined:

If any of these safer alternative designs [had] been used for Mrs. Chrastecky, she would not have suffered the injuries I set forth in my report, as her injuries were caused by the specific design flaws of the Align discussed above and in my general report. The likelihood that the Align's design would cause Mrs. Chrastecky's injuries and damages and the gravity of those injuries and damages outweighed the burden on Bard of adopting such alternative designs and the adverse effects, if any, of such alternative designs on the utility of [the] Align product.

Id. at p. 71. Dr. Rosenzweig also testified in his deposition that the four safer alternative designs he identified were safer than the Align Device. *See* Dkt. No. 86-4 at p. 122-25.

Bard also argues that none of the proposed alternatives are alternative designs, but rather are alternative procedures or products that cannot support an alternative design claim. But as Plaintiffs point out, "Bard has made, and lost, this argument many times before." Dkt. No. 86 at p. 10. For example, in *Reno v. C. R. Bard, Inc.*, 2016 WL 7155771, at *4 (S.D. W. Va. Dec. 7, 2016), Judge Goodwin reasoned as follows:

Bard also argues that the plaintiffs have presented no evidence of a safer alternative design. The plaintiffs, however, note that they have suggested that Bard's Align product could have been designed with larger pore sizes, could have been designed with rounder, thinner arms, or could have been made, in part, with native tissue. According to the plaintiffs, these design alternatives would have made the Align a safer product. Bard argues that these are new products, and such products do not demonstrate a "safer alternative design." At a minimum, the plaintiffs have established that there is a genuine dispute over whether their suggestions for the Align amount to a safer, alternative design.

Bard presents no other argument on design defect. Thus, Bard has failed to meet its burden under the summary judgment standard of showing the absence of a genuine dispute as to any material fact.

See also Dahse v. C. R. Bard, Inc., 2016 WL 7155770, at *4 (S.D. W.Va. Dec. 7, 2016). Bard's criticisms of Dr. Rosenzweig's opinions regarding safer alternative designs is an issue for the jury,

not this Court. This Court "may not make credibility determinations or weigh the evidence" in ruling on a motion for summary judgment." *Reeves*, 530 U.S. at 150.

The Court finds that Dr. Rosenzweig's Expert Report and testimony provide sufficient evidence to create a material issue of fact as to whether safer alternative designs existed. Accordingly, Bard's Motion for Summary Judgment should be denied as to this claim.

C. Negligence Claims

Next, Bard argues that it is entitled to summary judgment on Plaintiffs' claims for negligent inspection, marketing, packaging, and selling because Plaintiffs have adduced no evidence to support those claims. The Court agrees.

To prevail on these negligence claims, Plaintiffs are required to establish four elements: (1) a duty by the defendant to act according to an applicable standard of care; (2) a breach of the applicable standard of care; (3) an injury; and (4) a causal connection between the breach of care and the injury. *Perez v. Goodyear Tire & Rubber Co.*, 2016 WL 1464768, at *9 (Tex. App.—San Antonio 2016, pet. denied). Expert testimony is required to establish the standard of care "when the alleged negligence is of such a nature as not to be within the experience of the layman." *FFE Transp. Servs., Inc. v. Fulgham*, 154 S.W.3d 84, 90-91 (Tex. 2004). "When the conduct at issue involves the use of specialized equipment and techniques, expert testimony must establish both the standard of care and a violation of that standard." *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 211 (Tex. App.—Dallas 2011, pet. denied).

Bard contends that Plaintiffs have failed to adduce any evidence, expert or otherwise, to support their claims that Bard breached the applicable standard of care in the manner it inspected, marketed, packaged, or sold the Bard Device. In response, Plaintiffs fail to cite any summary judgment evidence, instead stating only that "the same evidence" supports Plaintiffs' product liability and negligence claims. This is insufficient to sustain their burden to show that a material

fact issue exists on these negligence claims. *See Dahse*, 2016 WL 7155770, at *5 (granting Bard's motion for summary judgment where, "apart from reciting allegations that form the plaintiffs' failure to warn and design defect claims, the plaintiffs do not offer any support that Bard breached a legal duty that caused the plaintiffs' injuries in their 'inspection, marketing, labeling, packaging, or selling' of the Align"); *Reno*, 2016 WL 7155771, at *5 (same).

D. Loss of Consortium

Bard argues that Plaintiff Michael Chrastecky's loss of consortium claim must be dismissed because the underlying tort claims in this case fail. Bard is correct that under Texas law, "a loss of consortium claim is derivative of the tortfeasor's liability to the physically injured spouse." *Barker v. Halliburton Co.*, 645 F.3d 297, 299 (5th Cir. 2011) (citing *Whittlesey v. Miller*, 572 S.W.2d 665, 667 (Tex.1978)). Because the Court is not recommending dismissal of all of Plaintiffs' tort claims, however, this argument fails.

E. Punitive Damages

Similarly, Bard contends that Plaintiffs' claim for punitive damages must be dismissed because all of Plaintiffs' underlying causes of action fail. This argument also should be rejected because the Court is not recommending dismissal of all of Plaintiffs' claims in this case.

F. Abandoned Claims

Finally, Bard contends that Plaintiffs' strict liability manufacturing defect claim (Count III) fails as a matter of law because Plaintiffs have not proffered any evidence to support the existence of a manufacturing defect in the Align Device. Bard also argues that Plaintiffs' breach of express and implied warranty claims (Counts V and VII) fail as a matter of law because Plaintiffs did not provide notice of any breach of warranty prior to filing suit.

Plaintiffs fail to respond to these arguments. When a party fails to pursue a claim or defense beyond the party's initial pleading, the claim is deemed abandoned or waived. *Black v. North*

Panola Sch. Dist., 461 F.3d 584, 588 n.1 (5th Cir. 2006) (plaintiff abandoned claim when she failed to defend claim in response to motion to dismiss); Arias v. Wells Fargo Bank, N.A., 2019 WL 2770160, at *2 (N.D. Tex. July 2, 2019) ("When a plaintiff fails to defend a claim in response to a motion to dismiss or summary judgment motion, the claim is deemed abandoned."). Bard is entitled to summary judgment on these claims due to Plaintiffs' abandonment.

G. Conclusion

Based on the foregoing, the Court finds that Bard's Motion for Complete Summary Judgment should be granted in part and denied in part. The Court recommends granting summary judgment with regard to Plaintiffs' negligence, strict liability manufacturing defect, breach of express warranty, and breach of implied warranty claims. Plaintiffs' strict liability design defect, strict liability failure to warn, loss of consortium, and punitive damages claims remain pending.

IV. RECOMMENDATION

Based on the foregoing, the undersigned **RECOMMENDS** that Defendant's Motion for Summary Judgment (Dkt. No. 69) is **GRANTED IN PART** and **DENIED IN PART**. The undersigned **RECOMMENDS** that the District Court **GRANT** the Motion with regard to Plaintiffs' claims for negligence, strict liability manufacturing defect, breach of express warranty, and breach of implied warranty claims, and **DENY** the Motion as to Plaintiffs' strict liability design defect, strict liability failure to warn, loss of consortium, and punitive damages claims.

V. WARNINGS

The parties may file objections to this Report and Recommendation. A party filing objections must specifically identify those findings or recommendations to which objections are being made. The District Court need not consider frivolous, conclusive, or general objections. *See Battle v.*

¹ Beyond its general causation argument, Bard did not move separately for summary judgment with regard to the Plaintiffs' strict liability failure to warn claim.

United States Parole Comm'n, 834 F.2d 419, 421 (5th Cir. 1987). A party's failure to file written objections to the proposed findings and recommendations contained in this Report within fourteen (14) days after the party is served with a copy of the Report shall bar that party from de novo review by the District Court of the proposed findings and recommendations in the Report and, except on grounds of plain error, shall bar the party from appellate review of unobjected-to proposed factual findings and legal conclusions accepted by the District Court. See 28 U.S.C. § 636(b)(1); Thomas v. Arn, 474 U.S. 140, 150-53 (1985); Douglass v. United Servs. Auto. Ass'n, 79 F.3d 1415, 1428-29 (5th Cir. 1996) (en banc).

SIGNED on February 14, 2020.

SUSAN HIGHTOWER

UNITED STATES MAGISTRATE JUDGE